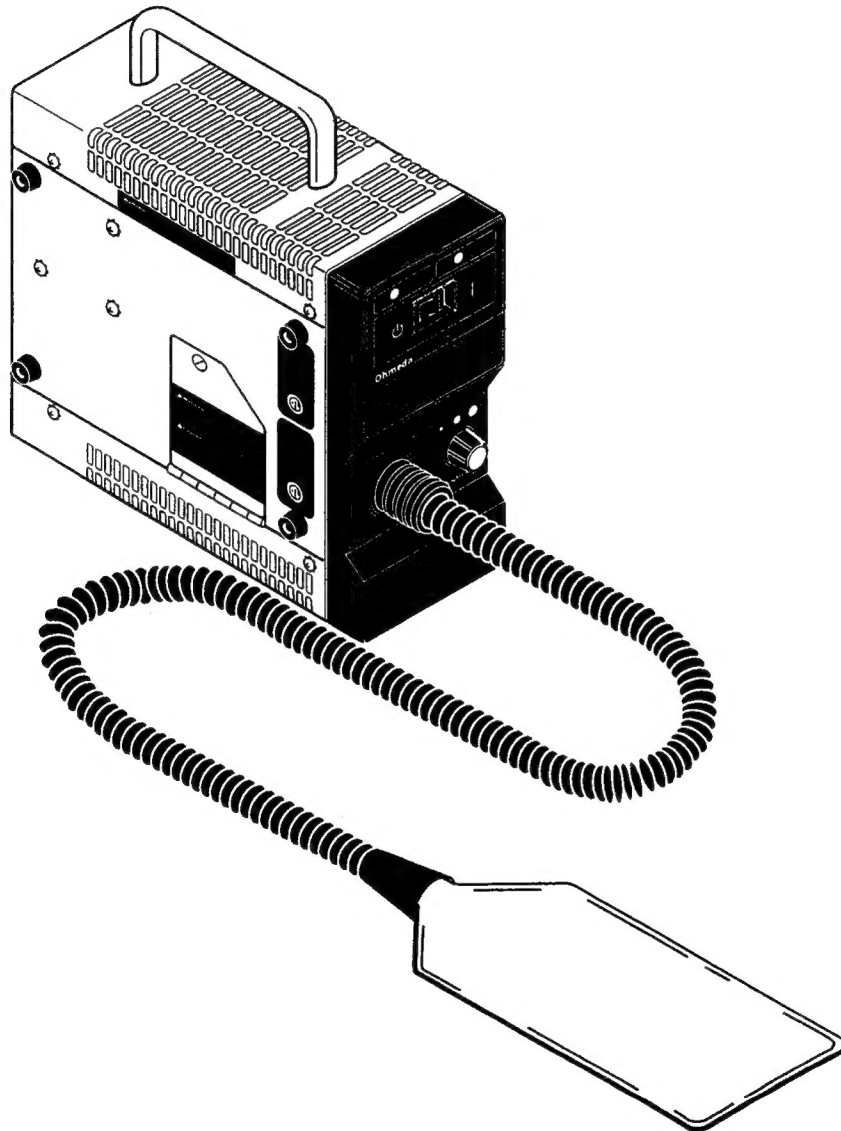




BiliBlanket™ Phototherapy Light

Operation, Maintenance, and Service Manual



User Responsibility

This Product will perform in conformity with the description thereof contained in this operating manual and accompanying labels and/or inserts, when assembled, operated, maintained and repaired in accordance with the instructions provided. This Product must be checked periodically. A defective Product should not be used. Parts that are broken, missing, plainly worn, distorted or contaminated should be replaced immediately. Should such repair or replacement become necessary, Ohmeda recommends that a telephonic or written request for service advice be made to the nearest Ohmeda Regional Service Center. This Product or any of its parts should not be repaired other than in accordance with written instructions provided by Ohmeda and by Ohmeda trained personnel. The Product must not be altered without the prior written approval of Ohmeda's Safety Department. The user of this Product shall have the sole responsibility for any malfunction which results from improper use, faulty maintenance, improper repair, damage or alteration by anyone other than Ohmeda.

CAUTION: Federal law in the USA and Canada restricts this device to sale by or on the order of a licensed medical practitioner.

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Precautions

Definitions

What the attention symbol means

In the left column, across from each warning or caution, we have placed an "attention, read accompanying documents" symbol to alert you to the presence of these important statements. This is the attention symbol:



When the attention symbol appears in front of text that is printed on the system itself, it means that the text is elaborated upon in the operation manual.

⚠WARNING: A Warning statement is used when the possibility of injury to the patient or the operator exists.

⚠CAUTION: A Caution statement is used when the possibility of damage to the equipment exists.



This symbol indicates the Standby position of the On/Standby switch.



This symbol indicates the On position of the On/Standby switch.



Indicates alternating current.



Indicates IEC Type B equipment.



This letter appearing before a fuselink value indicates a time delay fuselink.

Important: An Important statement is similar to a note but is used for greater emphasis.

Note: A Note provides additional information to clarify a point in the text.

The following Warnings and Cautions appear throughout the manual and are summarized here.

⚠ WARNINGS

Do not turn on or operate the BiliBlanket Phototherapy Light in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.

Precautions

A hot surface is exposed when the fiber optic cable is disconnected from the illuminator port. Do not insert fingers or foreign objects into the illuminator port whether the lamp is on or off.

Cover the patient's eyes when using the BiliBlanket Phototherapy Light to shield them if there is a concern of exposure to direct light from the BiliBlanket light pad. (This may not be necessary: • when using the vest, • when the pad can be maintained on the patient's back, • when the baby is clothed after applying the pad to the baby's chest or abdomen or • when additional conventional phototherapy is used.)

Verify that the illuminator power cord is disconnected from the power source before cleaning and that the unit is completely dry before using it.

Disconnect the power cord from the power source before opening the lamp access panel.

Allow the lamp to cool for at least ten minutes before attempting to remove it.

Do not operate the lamp with the protective compartment door open. The lamp operates under pressure and high temperature and may shatter.

Service described in this manual must be performed by a technically competent individual as described in this manual. Detailed drawings and procedures for more extensive repairs are included in this manual solely for the convenience of qualified personnel having proper knowledge, tools and test equipment, or for Ohmeda service representatives.

For protection against fire hazard, replace a fuse only with the correct type and rating of fuse as listed in section 6/Specifications.

ELECTRICAL SHOCK HAZARD! Do not remove the BiliBlanket Phototherapy Light's cover without first disconnecting the power cord.

⚠ CAUTIONS

To ensure the proper operation and light intensity, replace the lamp only with the proper lamp as listed in section 6/Specifications. Use of other lamps will affect the performance of and may result in damage to the BiliBlanket Phototherapy Light.

The lamp life is greatly reduced if it, or the Illuminator, is subjected to shock or bumping.

Do not allow the fiber optic cable or pad to rub on sharp or abrasive surfaces. The protective coverings may be damaged.

Observe the following fiber optic cable and pad assembly guidelines:

Precautions

- If you hang the fiber optic cable and pad assembly for temporary storage on an IV pole, door, wall hook or similar item, *do not pull* the cable when removing it for use. Carefully lift the cable free of obstructions when ready to use it.
- Do not lay the fiber optic cable where it could be crushed.
- Do not place anything on the fiber optic cable.

Not observing the guidelines may cause excessive stress and may:

- damage the cable's outer protective conduit,
- damage the cable's optical fibers,
- decrease light intensity at the light pad.

Do not block the air intake or outlet.

Do not scratch or soil the light-input end of the connector cable. Do not put sharp or heavy objects on the fiber optical pad, vest or connecting cable.

Never immerse the illuminator in liquid. The electronic circuitry can be short-circuited, causing permanent damage.

Never immerse the pad, vest or connecting cable in liquid.

Use the cleaning solution sparingly on a cloth when cleaning the exterior of the illuminator. Do not saturate the unit - excessive solution may flow into the illuminator causing damage to internal components.

Do not use a phenolic compound based cleaner. Phenolic compounds have been associated with elevated bilirubin levels in infants. Do not use cleaning solutions with an iodine base or any solution which discolors the pad. A discolored light pad will reduce the amount of light output.

Insulation on electrical wiring can deteriorate with age. Check for brittle or deteriorated insulation on power cord and all other electrical wiring.

Servicing of this product in accordance with this service manual should never be undertaken without the proper tools, test equipment and the most recent revision of this service manual which is clearly and thoroughly understood.

1/General Information



WARNING: Do not turn on or operate the BiliBlanket Phototherapy Light in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.

General Information

This manual describes how to checkout, operate and maintain the Ohmeda BiliBlanket Phototherapy Light. It also describes for the technically competent person how to service the BiliBlanket.

Before using the BiliBlanket Phototherapy Light

- Read through sections one through four of this manual.
- Pay special attention to the Warnings and Cautions which appear in the manual and are summarized in the Precautions section.
- Read the User Responsibility statement located on the inside front cover; it describes what is expected of the user to maintain a safe and accurate product.
- Read the Warranty; it describes Ohmeda's responsibility in case of a functional defect.

Keep this manual available for answering questions which may arise.

Description

The Ohmeda BiliBlanket Phototherapy Light uses a fiber optic cable to deliver light from a high intensity lamp to a woven fiber optic pad which is placed in a disposable cover that is in contact with the patient. The patient is exposed to light in the ideal 400 to 550 nanometer range for phototherapy treatment.

The BiliBlanket system consists of an illuminator unit and a light pad with a four foot long fiber optic cable. The illuminator unit contains a light source, light filters, a variable power supply for the light source, a cooling system and overheating protection near the light source.

The illuminator light source is a high intensity, tungsten halogen lamp with a built-in reflector. The reflector is coated with a dichromatic surface which reduces the infrared energy transmitted. This lamp is specifically selected for use with the BiliBlanket. A light filter, positioned in front of the lamp, rejects light outside the 400 to 550 nanometer range. This filtered light is focused on the inlet of the fiber optic cable.

Three light intensities are selectable by the front panel brightness selector rotary switch: high, medium and low. Table 1-1 shows the typical light output values.

1/General Information

Table 1-1 - BiliBlanket
light output values

Switch position:	*Typical light output:
High	35 $\mu\text{W}/\text{cm}^2/\text{nm}$
Medium	25 $\mu\text{W}/\text{cm}^2/\text{nm}$
Low	15 $\mu\text{W}/\text{cm}^2/\text{nm}$

* See Light Output Measurement Procedures on Page 5-16

Supply power

Power for the illuminator can be supplied by any standard 100, 120, 220 or 240 volt AC mains power source at either 50 or 60 Hz. Power enters the illuminator through a receptacle which has an integral fuseholder and a mains power voltage selector. The voltage selector/fuseholder on the back of the illuminator must be set to the voltage of the power source which is being used before connecting the power cord to the power source. The fuses must have the proper rating for the voltage of the power source which is being used. See section 6/Specifications for the proper fuse rating.

Cooling

A fan cools the illuminator. A thermal cutout switch located next to the light filter protects the illuminator and fiber optic cable from overheating.

Fiber optic cable

The fiber optic cable contains over 2000 individual plastic fibers which transmit the light from the illuminator to the light pad. The light pad is constructed by weaving these fibers into a mat. This patented process produces a pad with light over the entire surface. A disposable protective cover for the pad is provided to reduce the risk of cross-contamination and to enhance the patient's comfort.

Disposable cover

The disposable cover is designed for use with both premature and full-term infants. The infant lies directly on the disposable-covered pad without any method of attachment to retain the pad to the infant.

Disposable vest

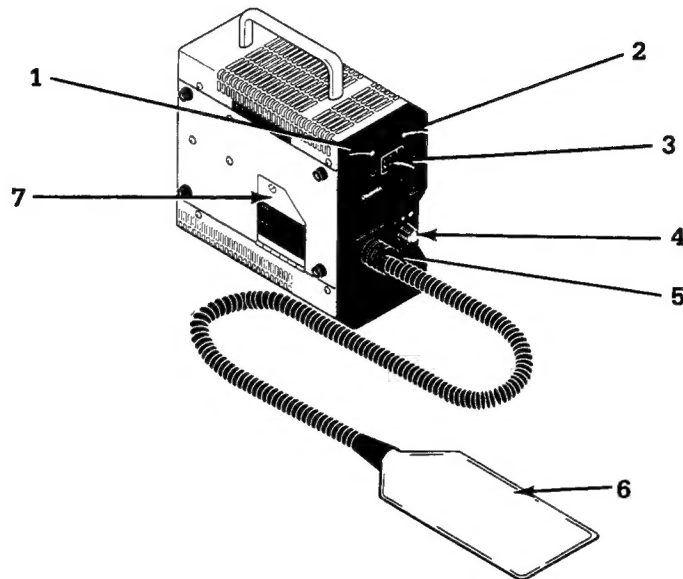
A disposable vest is designed for use with full-term infants who can tolerate having the strap fastened around the midsection. With the disposable vest, it is possible to hold and nurse the infant while continuing the treatment. For premature infants and full-term infants who can't tolerate having the vest secured around the midsection, the disposable cover should be used.

1/General Information

Illuminator controls, indicators and connectors

Illuminator and pad

Figure 1-1
Illuminator and pad



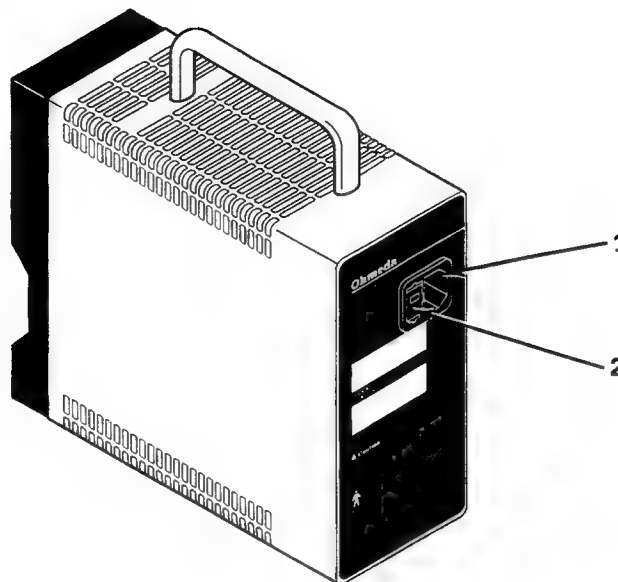
Refer to figure 1-1.

Power indicator	1. The green light-emitting diode (LED) illuminates when the illuminator power is on.
Air flow failure indicator	2. The yellow light-emitting diode (LED) illuminates when there is an air flow failure.
On/standby switch	3. The on/standby switch switches the illuminator on.
Brightness selector	4. The three-position rotary switch selects the High, Medium or Low light intensity. (See table 1-1 for light intensity values.)
Illuminator port	5. The illuminator port is for attaching the fiber optic cable connector.
Pad assembly	6. The pad assembly attaches to the illuminator port. Light is fed through the optical fiber cable to the optical fiber woven pad.
Lamp replacement door	7. The lamp replacement door on the left side panel allows access to the illuminator lamp. Refer to section 3/Maintenance for information on replacing the lamp.

1/General Information

Illuminator back panel

Figure 1-2
Illuminator back panel



Refer to figure 1-2.

Power cord receptacle

1. The power cord plugs into the power cord receptacle.

Voltage selector/fuseholder module

2. The voltage selector/fuseholder module allows setting the illuminator to the proper voltage rating available from the wall power source. It also contains the fuses for the illuminator. Refer to section 4/Service Procedures for information on replacing a fuse or for information on setting the illuminator to the correct local line voltage.

Accessories and replacement parts

Table 1-2 - Accessories and replacement parts

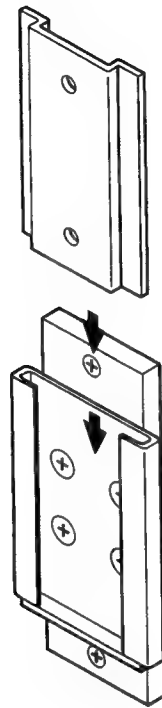
Item:	Stock number:
Carrying case	6600-0213-800
Disposable covers (carton of five bags of ten covers)	6600-0270-200
Disposable vest (carton of ten bags of five vests)	6600-0461-200

1/General Information

Fuse assortment, 100/120, 220/240 VAC: Five fuses: 3.15 A (5 x 20 mm) time delay, Five fuses: 1.60 A (5 x 20 mm) time delay, Five fuses: 10.0 A (.25" x 1.25") fast acting.	6600-0287-200
Illuminator lamp (carton of six lamps)	6600-0262-200
Mobile stand, less adaptor	6700-0025-800
Mobile stand slide bracket assembly, female	6700-0014-800
Operation, Maintenance and Service manual	6600-0099-000
Pad assembly	6600-0167-800
Power cord, 100 V - 120 V	6600-0282-200
Power cord, 220 V	6600-0283-200
Power cord, 240 V	6600-0284-200
Rail mount slide bracket kit, female	6600-0031-900
Repair kit for the fiber optic cable cover	6600-0239-800
Replacement lamps (6)	6600-0262-200
Slide mounting bracket accessory; attaches to two of the mounting screws on the left side of the illuminator. Allows hanging the illuminator from a Bird blender bracket (see figures 1-3 and 4-3).	6600-0198-800

1/General Information

Figure 1-3
Slide mounting
bracket accessory
slides into a Bird
blender bracket



2/Operation



WARNING: Do not turn on or operate the BiliBlanket Phototherapy Light in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.

Factors which affect light output and life

Lamp light output and life are affected by various factors among which are:

- Available line voltage
- Lamp variations
- Brightness selector setting
- Vibration and mechanical shock
- Non-recommended lamp

Available line voltage

The available line voltage will affect the light output and the life of the illuminator lamp. Table 2-1 provides an example.

Table 2-1 - Effect of line voltage on lamp light output and life

Line voltage:	% of desired light output:	Predicted lamp life hours at High switch setting*:	Lamp wattage:
-10%	69%	700	126
nominal	100%	300	140
+10%	141%	65	176

*continuous operation

Lamp variations

The light output from lamp to lamp may vary by as much as 10%.

Intensity setting

The lamp life will vary greatly with the intensity at which the illuminator is operated. Table 2-2 provides an example.

Table 2-2 - Brightness selector switch setting effect on lamp life

Brightness selector switch setting:	Typical lamp life hours:*
Low	1875
Medium	450
High	300

*continuous operation at nominal voltage

2/Operation

Vibration and
mechanical shock

Vibration and mechanical shock will significantly reduce the lamp life. Care should be taken when moving the illuminator. To maximize the lamp life, the illuminator should be mounted or placed on a surface which is stable and not exposed to vibration.

Non-recommended
lamps

Using any lamp other than that recommended and distributed by Ohmeda for the BiliBlanket system will affect the performance of and may result in damage to the illuminator or the fiber optic pad.



CAUTION: To ensure the proper operation and light intensity, replace the lamp only with the proper lamp as listed in section 6/Specifications. Use of other lamps will affect the performance of and may result in damage to the BiliBlanket Phototherapy Light.

Checkout procedure before operation

Before operating the Ohmeda BiliBlanket Phototherapy Light, the following steps should be taken to ensure that the BiliBlanket will provide effective phototherapy treatment. This checkout procedure assumes that you are familiar with the unit's controls.



CAUTION: Do not allow the fiber optic cable or pad to rub on sharp or abrasive surfaces. The protective coverings may be damaged.



CAUTION: Observe the following fiber optic cable and pad assembly guidelines:

- If you hang the fiber optic cable and pad assembly for temporary storage on an IV pole, door, wall hook or similar item, *do not pull* the cable when removing it for use. Carefully lift the cable free of obstructions when ready to use it.

- Do not lay the fiber optic cable where it could be crushed.

- Do not place anything on the fiber optic cable.

Not observing the guidelines may cause excessive stress and may:

- damage the cable's outer protective conduit,
- damage the cable's optical fibers,
- decrease light intensity at the light pad.

Checkout procedure

1. Place the illuminator on a flat, level surface (or use the mounting slide bracket) to locate the illuminator within a few feet of the treatment location.
2. Verify that the air circulation vents on the top and the bottom of the illuminator are unobstructed.

2/Operation



CAUTION: Do not block the air intake or outlet.

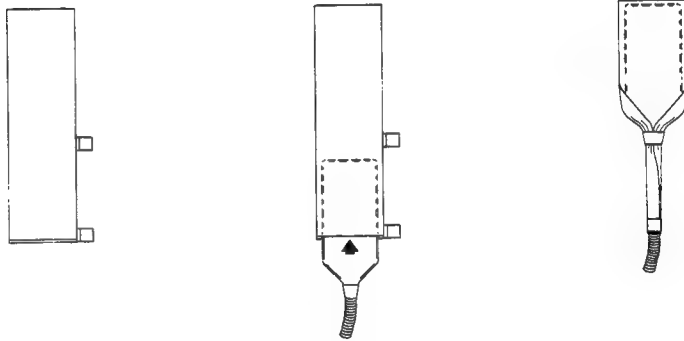
3. Verify that the proper voltage label shows on the voltage selector/fuseholder (on the rear panel).
4. Connect the power cord to the illuminator first and then to the line power supply.
5. Fully engage the fiber optic cable connector into the illuminator port.



CAUTION: Do not scratch or soil the light-input end of the connector cable. Do not put sharp or heavy objects on the fiber optical pad, vest or connecting cable.

6. Insert the light pad into a new, disposable cover or vest and secure the cover or vest around the fiber optic cable with the self-adhesive tabs. Refer to figures 2-1 and 2-2. The adhesive side of the tabs must be facing in the same direction as the pad's primary light side.

Figure 2-1
Inserting the light
pad into the cover



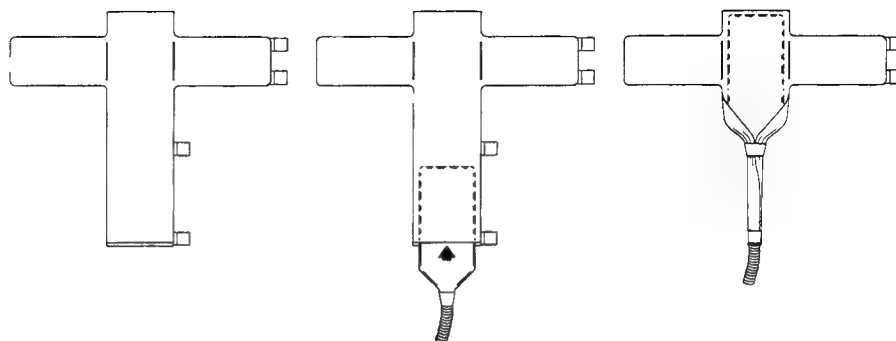
1. Disposable cover
for the light pad.

2. Inserting the light
pad into the cover.

3. Adhesive tabs
fastened around the
optic cable.

2/Operation

Figure 2-2
Inserting the light
pad into the vest



1. Disposable vest for the light pad.
 2. Inserting the light pad into the vest.
 3. Adhesive tabs fastened around the optic cable
-

7. Switch on the on/standby switch.
8. Using the brightness selector switch on the front panel, select each of the light intensity settings and ensure that light is being emitted from the pad.
9. Switch off the power.



WARNING: A hot surface is exposed when the fiber optic cable is disconnected from the illuminator port. Do not insert fingers or foreign objects into the illuminator port whether the lamp is on or off.

Operation using the disposable cover



WARNING: Cover the patient's eyes when using the BiliBlanket Phototherapy Light to shield them if there is a concern of exposure to direct light from the BiliBlanket light pad. (This may not be necessary: • when using the vest, • when the pad can be maintained on the patient's back, • when the baby is clothed after applying the pad to the baby's chest or abdomen or • when additional conventional phototherapy is used.)

2/Operation

The disposable cover is designed for use with both premature and full-term infants. The infant lies directly on the disposable-covered pad without any method of attachment to retain the pad to the infant.

The infant, along with the light pad, may be covered or wrapped in a blanket. The infant will continue to receive effective phototherapy treatment as long as the disposable-covered, light-emitting section of the pad remains in contact with the skin.

The disposable cover should be the only material between the light-emitting side of the pad and the infant's skin. If the disposable cover becomes soiled, it should be replaced with a new cover. The disposable cover should also be replaced between patients.

Operation using the disposable cover

1. If the BiliBlanket Phototherapy system is used with an infant in an incubator, a warmer or a bassinet, the illuminator should be placed on a shelf or mounted using the mounting bracket near the treatment site. When using an incubator, the fiber optic cable should be inserted through the access port or porthole and the pad placed on the mattress. The illuminator should *never* be placed inside the infant compartment of the incubator, warmer or bassinet.
2. Be sure the light pad is covered with a new disposable cover secured around the fiber optic cable with the tape tabs as shown in figure 2-1. The adhesive side of the tabs must be facing in the same direction as the pad's light-emitting side when the pad is inserted into the cover.
3. Place the pad on the mattress with the light-emitting side up.
4. Perform the checkout procedure for the BiliBlanket Phototherapy Light.
5. Place the infant with the bare back or bare stomach directly on the light-emitting section of the pad with the fiber optic cable end of the pad at the infant's feet. See figure 2-3.

Cover the patient's eyes when using the BiliBlanket Phototherapy Light to shield them if there is a concern of exposure to direct light from the BiliBlanket light pad.

Assure that:

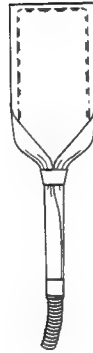
- there is nothing between the infant's skin and the light pad other than the disposable cover.
- as much of the infant's skin is in contact with the disposable-covered, light-emitting section of the pad as is practical.

2/Operation

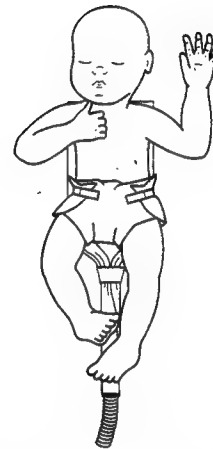
Note: It is the light from the pad penetrating the outer few millimeters of the skin which results in the isomerization of the bilirubin molecule.

Important: The disposable-covered, light-emitting area of the pad must make physical contact with the infant's skin. Remove or reposition infant's clothing that could interfere with the light path.

Figure 2-3
Placing the infant
onto the pad with
cover



1. Light pad covered with the disposable cover.



2. Infant placed on the light pad covered with the disposable cover.

-
6. The infant, along with the light pad, may be covered or wrapped in a blanket. The infant will continue to receive effective phototherapy treatment as long as the disposable-covered, light-emitting section of the pad remains in contact with the skin.

The disposable cover should be the only material between the light-emitting side of the pad and the infant's skin. If the disposable cover becomes soiled, it should be replaced with a new cover. The disposable cover should also be replaced between patients.

7. Verify that the illuminator is plugged into a suitable power outlet. Switch on the illuminator power switch and set the brightness selector to the level desired.

Important: Do not bump or bounce the illuminator during operation. Such a physical shock can cause shattering and failure of the lamp.

8. When the treatment is completed, switch off the illuminator power switch, remove the patient from the pad and discard the pad cover.

2/Operation

Operation using the disposable vest



WARNING: Cover the patient's eyes when using the BiliBlanket Phototherapy Light to shield them if there is a concern of exposure to direct light from the BiliBlanket light pad. (This may not be necessary: • when using the vest, • when the pad can be maintained on the patient's back, • when the baby is clothed after applying the pad to the baby's chest or abdomen or • when additional conventional phototherapy is used.)

The disposable vest is designed for use with full-term infants who can tolerate having the vest straps fastened around the midsection. For premature infants and full-term infants who can't tolerate having the vest secured around the midsection, the disposable cover should be used.

Operation using the disposable vest

1. If the BiliBlanket Phototherapy system is used when an infant is in an incubator, a warmer or a bassinet, the illuminator should be placed on a shelf or mounted using the mounting bracket near the treatment site.

When using an incubator, the fiber optic cable should be inserted through the access port or porthole and the pad placed on the mattress. The illuminator should *never* be placed inside the infant compartment of the incubator, warmer or bassinet.

2. Be sure the light pad is inserted into a new disposable vest with the closure tab adhesive side facing the same direction as the light-emitting side of the pad. The vest should be secured around the fiber optic cable with the tape tabs as shown in figure 2-2.
3. Lay the disposable vest and light pad on a mattress or other flat surface with the strap section of the vest spread out and the light-emitting side of the pad facing up.
4. Perform the checkout procedure for the BiliBlanket Phototherapy Light.
5. Place the infant's bare back or bare stomach directly onto the disposable-covered, light-emitting section of the pad with the fiber optic cable end of the pad at the infant's feet. See figure 2-4.

Assure that:

- there is nothing between the infant's skin and the light pad other than the disposable vest.

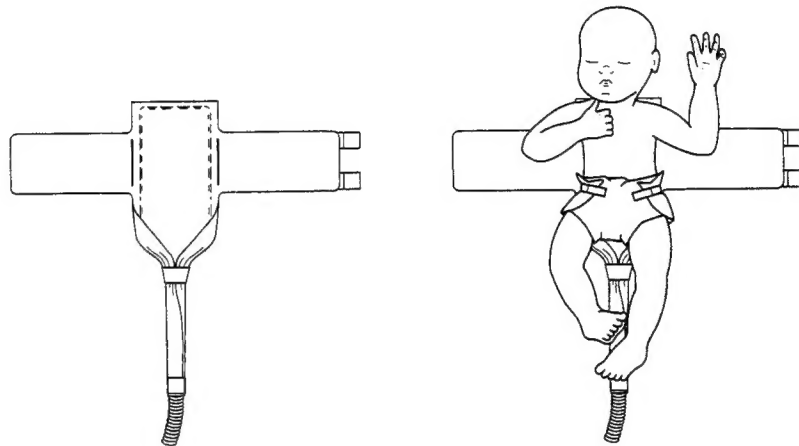
2/Operation

- as much of the infant's skin is in contact with the disposable-covered, light-emitting section of the pad as is practical.

Note: It is the light from the pad penetrating the outer few millimeters of the skin which results in the isomerization of the bilirubin molecule.

Important: The disposable-covered, light-emitting area of the pad must make physical contact with the infant's skin. Remove or reposition infant's clothing that could interfere with the light path.

Figure 2-4
Placing the infant
onto the pad with
vest



1. Light pad covered with the disposable vest.

2. Infant placed on the light pad covered with the disposable vest.

-
6. Wrap the strap section of the vest sufficiently tight around the infant's midsection to hold the pad and vest in position and secure it with the tape tabs.
 7. The infant may then be clothed or bundled in a blanket and will continue to receive effective phototherapy treatment as long as the lighted section of the disposable-covered pad remains in contact with the skin.

When using the disposable vest, it is possible to hold and nurse the infant while continuing the treatment.

If the disposable vest becomes soiled, it should be replaced with a new vest. The disposable vest should also be replaced between patients.

8. Verify that the illuminator is plugged into a suitable power outlet. Switch on the illuminator power switch and set the brightness selector to the level desired.

2/Operation

Important: Do not bump or bounce the illuminator during operation. Such a physical shock can cause shattering and failure of the lamp.

9. When the treatment is completed, switch off the illuminator power switch and remove the pad and vest. Remove and discard the disposable vest.

3/Maintenance

Maintenance schedule

Maintain the unit in accordance with the information below.

Operator maintenance

After each patient:	Replace the pad or vest.
Weekly or after each patient:	Clean the unit. Check the fan filter on the bottom of the illuminator (see figure 5-1) for lint and dust accumulation and vacuum clean if necessary.
Quarterly:	Clean the air filter.

Note: This is the minimum cleaning frequency. The air filter must be cleaned whenever it appears dirty, depending on the concentration of lint and dust in the operating environment.

Service maintenance

Quarterly:	Perform the electrical safety procedures detailed in section 5/Service Section.
	With a photometer, ensure that the required light output is being emitted from the pad.
	Refer to Light Output Measurement Procedures on Page 5-16.

Cleaning and disinfecting



WARNING: Verify that the illuminator power cord is disconnected from the power source before cleaning and that the unit is completely dry before using it.



CAUTION: Never immerse the illuminator in liquid. The electronic circuitry can be short-circuited, causing permanent damage.



CAUTION: Never immerse the pad, vest or connecting cable in liquid.



CAUTION: Use the cleaning solution sparingly on a cloth when cleaning the exterior of the illuminator. Do not saturate the unit - excessive solution may flow into the illuminator causing damage to internal components.

3/Maintenance

1. Unplug the power cord and allow the illuminator to cool for at least ten minutes.
2. Clean the exterior of the illuminator using a mild detergent solution applied with a damp cloth or sponge. Aqueous solutions which are both hospital disinfectants and mycobactericides may be used. A quaternary amine disinfectant-detergent registered by the U.S. Environmental Protection Agency may be used.

Do not allow liquids to seep into the housing.

Dry the illuminator surface with a clean, soft cloth.

3. The pad assembly may be cleaned without immersing by using a disinfecting agent safe for use on the materials. Aqueous solutions which are both hospital disinfectants and mycobactericides may be used. A quaternary amine disinfectant-detergent registered by the U.S. Environmental Protection Agency may be used.

Never use an abrasive cleaner on the pad, the cable or the connector.



CAUTION: Do not use a phenolic compound based cleaner. Phenolic compounds have been associated with elevated bilirubin levels in infants. Do not use cleaning solutions with an iodine base or any solution which discolors the pad. A discolored light pad will reduce the amount of light output.

The following table lists some cleaning solutions.

Table 3-1 - Cleaning and disinfecting solutions

Generic Formulation:	Maximum concentration level:
Hydrogen peroxide	6%
Sodium hypochlorite compound	100 parts/million
Quaternary ammonium	0.2%